PT. SINKO PRIMA ALLOY

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SPA-BM/PROD-180. 06 May 2025. Rev02

Daftar Isi

1. Summary

Jaundice is a common phenomenon in neonatal period, it is observed that Jaundice is a common phenomenon in neonatal period, it is observed that over 90% newborn babies have jaundice in different degree. It can be over 90% newborn babies have jaundice in different degree. It can be a physiological phenomenon (physiological jaundice) in neonatal period, or it can be an important symptom of many diseases in neonatal period (called pathological jaundice. This pathological jaundice can cause bilirubin brain illness (called kernicterus), it can cause brain damage of newborn baby, and results in early death and serious sequela, so we must take immediate and efficient measures to treat neonatal pathological jaundice.

The effect of phototherapy treatment for neonatal high bilirubin blood illness has been approved by clinic, its principle is that bilirubin can absorb rays to have actinic isomerization, it makes the indirect bilirubin oxidize into one water-soluble product under the bluish green light (light-oxidation bilirubin). It fades yellow according to liver and gallbladder discharging out of body. The medical field recognizes that using phototherapy to treat neonatal pathological jaundice is a simple and effective method. Neonatal phototherapy unit are also called “infant phototherapy device” or “blue light lamp”. It is necessary medical equipment of neonatal medical department.

1.1 Definition and Symbol

1.1.1 Definition

The terms and definitions of IEC 60601-2-50 "Medical Electrical Equipment Part 2: Special Requirements for the Safety of Infant Phototherapy Equipment" apply.

1. Effective surface

Place the patient according to the designated position on the surface irradiated by the phototherapy equipment.

2. Total bilirubin irradiance Ebi

The irradiance is equivalent to the irradiance evaluated in the range of 400nm～550nm, and is given by the following integral formula:

$$Ebi = \int_{400nm}^{550nm} E\lambda(\lambda)d\lambda$$

unit：μW/cm2 ， Where Eλ(λ) is the irradiance measured at each wavelength.

3. Uniformity of bilirubin total irradiance G2

The ratio of the minimum total bilirubin irradiance Ebi min and the maximum total bilirubin irradiance Ebi max on the effective surface is as follows:

G2 = Ebi min/EBi nmax

1.1.2 **Symbols**

	Eye Protection for the patients		Attention, Consult accompanying documents
	Power on		Power off
	Downside phototherapy on		Downside phototherapy off
	Type B application part		Downside phototherapy start/stop button

	Mode selection key		Clear key
	Add key		Reduce key
	Protective grounding		Recycle

1.2 Scope of application and contraindications

1.2.1 Scope of application

This product is used for light treatment of high bilirubin for newborn baby.

1.2.2 Contraindications

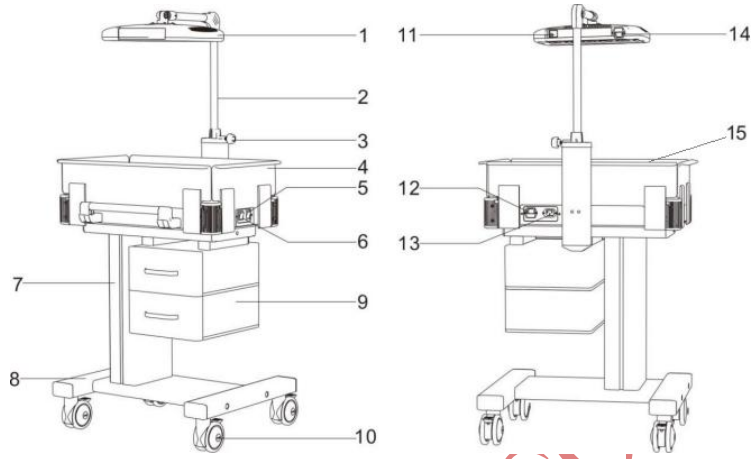
a) Do not use this product to irradiate patients whose temperature is too high (≥37.7℃)!

b) Prohibited patients with elevated bilirubin!

1.3 Structure composition and characteristics

1.3.1 Structure and composition

The BL-200 infant phototherapy instrument is composed of blue light, control box, crib, support rod and base. The main parts of the equipment are shown in the figure below:



1.Upside phototherapy control box	2. Support frame	3. Screw thread
4. Barrier	5. Master switch	6.Downside phototherapy switch
7.Base column	8. Base	9. Drawer
10. Wheel	11.Upside phototherapy switch	12.Upside phototherapy output socket
13.Total power input socket	14.Upside phototherapy input socket	15. Infant bed

Figure 1-1 Schematic diagram of the main structure

Part Name	Description
Base	Including brake casters, trays, base columns and drawers, carrying the weight of the crib and accessories.
Infant bed	Made of high-quality plexiglass, the maximum load-bearing weight is 100N.

Control box	An important part of the equipment is divided into upper blue light control box and lower blue light control box. A single control box is composed of a control box shell, a control circuit board and an operation panel. Used to control the blue light.
Drawer	Used to store medical supplies and documents. The maximum carrying capacity of a single drawer is 20N.

1.3.2 Features

1. Small size, light weight, high radiation efficiency.
2. Using electronic adapter, strong power adaptability.
3. The blue light LCD displays the treatment time.
4. Imported LED cold light source, with low attenuation and long life;
5. Upper blue light irradiance is adjustable in three levels: high, medium and low;
6. The upside blue light automatically saves 99999.9 hours of accumulated use time. The downside blue light automatically saves 9999.9 hours of accumulated use time.

1.4 Equipment classification

Figure 1-2 Equipment classification

Classified by type of electric shock prevention	Class I
Classified by degree of protection against electric shock	Type B
Classified according to the degree of protection against ingress of liquid	IPX4（The lower part of the infant bed）

Whether AP, APG type	Non-AP, APG equipment
Classified by operating mode	continue to operate

1.5 Working and transportation storage conditions

Figure 1-2 Working, Transportation and Storage

Working environment conditions	Atmospheric	700hPa～1060hPa
	Temperature range	+18℃～+30℃
	Humidity range	10%～85%RH
Environmental conditions for transportation and storage	Atmospheric	500hPa～1060hPa
	Temperature range	-10℃～+55℃
	Humidity range	≤95%

The outer packaging box of the product can be transported by general transportation means, and it should be handled with care when transporting, and it should be kept upright and moisture-proof during transportation.

1.6 Period of use

1. Product life: 6 years.
2. Production date: See product label.

2. Working principle

The phototherapy instrument is equipped with upper and lower blue light sources: the lower blue light acts on the surface of the baby's skin through transparent plexiglass; the upper blue light directly acts on the surface of the baby's skin. The distance between the upper blue light source and the baby can be adjusted by the adjustment frame, and then the irradiance can be adjusted, and the lower blue light can be used to achieve a higher therapeutic effect.

When the LED lamps of the upper and lower light sources emit blue light for treatment, they also produce a certain amount of heat radiation (about 2°C higher than the working environment temperature after the warm-up is stabilized). The upper and lower light sources have independent control parts. The medical staff can choose the appropriate irradiation mode and timing method according to the clinical needs, and check the baby's body temperature regularly to safely and effectively treat neonatal jaundice.

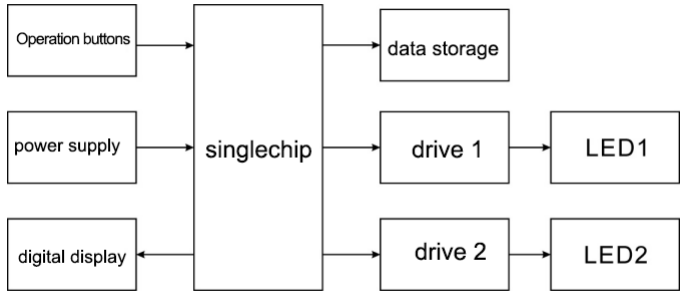


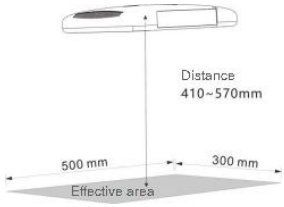
Figure 2-1 Block diagram of BL-200

3. Performance

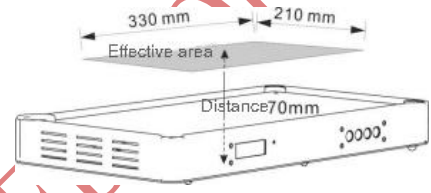
Product	BL-200			
Power supply	AC 220V±22V； 50Hz±1Hz			
Input power	35.7VA			
Life time of LED bulbs	≥20000 hours			
Radiant wave	440nm～480nm			
Height of upside phototherapy adjustable range	1300mm~1600mm (From light head to floor)			
Downside Phototherapy Unit:				
Highest total irradiance for bilirubin on effective area : 1500μW/cm²				
Upside phototherapy unit:				
	Radiation distance ：500mm , Efficiency radiation area: 600mm*300mm when		Radiation distance: 360 mm, Efficiency radiation area ： 500mm*300mm	
	Average of total irradiance for bilirubin (μW/c ㎡)	Highest total irradiance for bilirubin (μW/c ㎡)	Average of total irradiance for bilirubin (μW/c ㎡)	Highest total irradiance for bilirubin (μW/c ㎡)
H	1415	1620	2000	2800

M	1000	1200	1400	2000
L	400	480	620	800
Netto	±40 kg			

The effective surface size figure and its position relative to the equipment are shown in the figure below:



Gambar 6-1 Figure 6-1 The effective surface size graph and its position relative to the device relatif terhadap perangkat



Gambar 6-2 The effective surface size of blue light and its position relative to the device

4. Function description

4.1 Main function or working mode

There are 3 working modes for blue light on this machine: high-end mode: all lamp beads are on; mid-range mode: 12 lamp beads are on; low-end mode: 5 lamp beads are on. Adjust the mode by pressing the button , and switch the sequence: low gear → medium gear → high gear → pause → low gear; there are corresponding symbols in the display to indicate the current working mode, as shown in the figure below, when all 3 symbols are solid, it is high mode; two solids When one is hollow, it is in mid-range mode; when one is solid and two are hollow, it is in

low-range mode; when all three are hollow, the LED lamp beads are temporarily turned off, which is the pause state.

Note: After turning off the power switch or cutting off the power, turn on the machine again, and the machine will automatically implement the radiation intensity mode that was counted last time.

The downside phototherapy irradiance of this machine is not adjustable.

4.2 The main function

a. Positive timing mode: This mode runs by default when it is turned on;

b. Countdown mode: long press the "decrease button" to switch to this mode for operation;

c. The countdown time can be set according to needs, and the step length can be adjusted in 30 minutes;

d. You can view the accumulated use time;

e. The timer can be reset to zero;

f. The brightness of the upper blue LED lamp bead is adjustable in 3 levels, and the lower blue light is not adjustable.

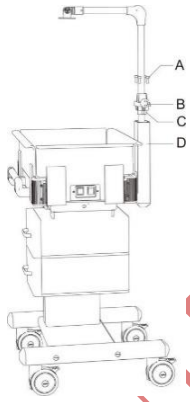
5. Installation

When unpacking, please count all parts according to the packing list (P20) in the manual, and be careful not to damage or lose each part.

5.1 Installation steps of the whole machine

5.1.1 Assembly of support frame

As shown in the figure below, loosen the threaded handle, slide the rotary sliding seat on the support frame to a suitable position, insert the rotary sliding seat into the support frame column according to the direction shown in the figure, and use 4 M8*30 inner hexagonal bolts (not included Flat washer and spring washer) locked, pay attention to the direction of the rotating slide, as shown in the figure, facing the equipment threaded handle on the right.



A. M8*30 inside hexagonal bolt
B. Screw thread
C. Rotating slide
D. Rotating slide

Figure 5-1 Assembling the support frame

5.1.2 Instalasi *adjust support* dan sumber fototerapi

K Take out the upper blue light box from the small packaging carton, and use 4 M4*12 countersunk screws to connect it to the fixed base firmly. Note that the display part of the light box is at the front and do not install it backwards; as shown in the figure below.

A. M4*12 screw

B. Fixed base

C. Fixed base

D. Up phototherapy source

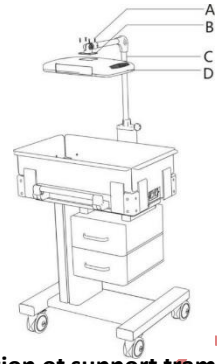
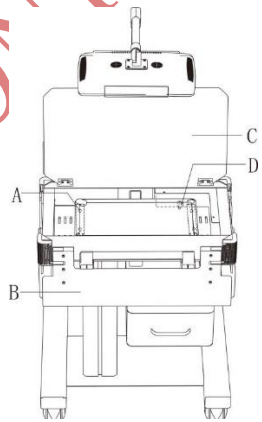


Figure5-2 Installation of support frame and upside phototherapy

5.2 Downside phototherapy installation

Open (lift up and then tilt to the periphery) the crib baffle, and open the transparent plexiglass. Take the lower blue light out of the carton and put it into it, making sure that the lower blue light feet are put into the lower blue light positioning holes. Insert the power adapter plug into the corresponding socket on the right front of the downside phototherapy.



A. Downside phototherapy light positioning hole

B. Barrier

C. Transparent plexiglass

D. Power adapter plug

Figure 5-3 Downside phototherapy installation

6 Instruction for use

6.1 Preparation before operation

1. The cleaning work must be done before use, especially the lens surface must be free of dirt, so as not to affect the light effect.

2. Move the machine to the position required by the patient, adjust the height and illumination angle of the upper blue light box, and tighten the threaded handle.

The following are several adjustment states and adjustment ranges when the product is in use, as shown in Figure 6-1.

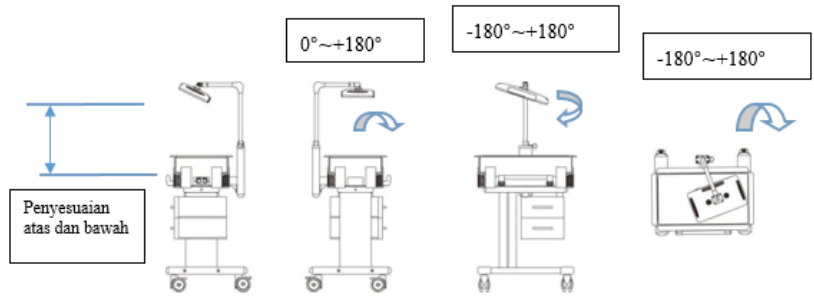
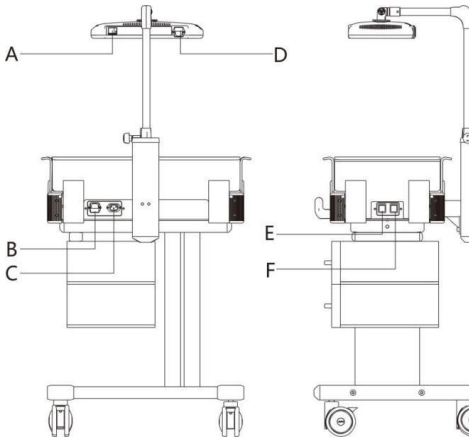


Figure 6-1 Schematic diagram of angle adjustment

3. Insert one end of the power cord into the main power input socket on the back of the machine, and the other end into the hospital's AC 200V±22V, 50Hz±1Hz network power three-hole socket (the grounding wire in the socket must be reliably grounded), and the blue light input and The output socket is connected with the corresponding power cord, as shown in Figure 6-2 below:



A.Upside phototherapy switch

B. Upside phototherapy switch

C.Upside phototherapy input socket

D. Upside phototherapy onput socket

E.Upside phototherapy switch

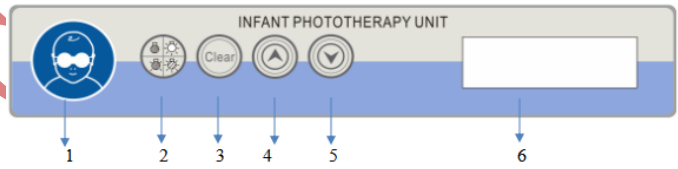
F. Main power switch

Figure 6-2 Schematic diagram of power cord connection

4. After protecting the child with eye mask and perineal mask, limit the child to the effective surface area of the phototherapy light box and turn on the power switch of the phototherapy light box. The LED lamp bead in the blue light box lights up, the timer starts timing, and the treatment begins.

6.2 Introduction and use of operation panel

6.2.1 Introduction to the phototherapy unit



1 protect label	2 Irradiation intensity adjustment key	3 Clear key
4 Add key	5 Reduce key	6 Display screen

Figure 6-3 .Up phototherapy panel

After the device is turned on and lighted up, it automatically starts timing; when the device is in the paused state, the timer stops timing and displays the current exposure time in the format of "hour: minute: second"; press the button  again, the blue light bead continues Lights up, and the timer continues to keep this time.

The phototherapy instrument has the functions of turning off the blue light at a fixed time and accumulating time. When there is no timing setting, the default phototherapy time is 100 hours, and it will stop automatically when the time comes. The accumulative timer function displays the total light therapy time from the first use to the current use, displayed in the format of "XXXXX.X" hours, and the maximum accumulated time is 99999.9 hours.

Timer reset: press and hold the 

key for 5 seconds, the timer will reset the current use time to zero.

Set the time for phototherapy (turn off the lamp on time).

a) press  key some seconds, enter count down mode, default value is 1 hour. Then can press  or  to increase or reduce count down time. The range is : 30 minutes *n (n=1-96),when n=97 and display 0, then the range of irradiate time is 00:30:00-48:00:00’

b) if set the irradiate time when the lamp is lighten, then the irradiance level not change; if set the irradiate time when the lamp paused, then the irradiance level is high level. And the timer is starting count down till display 0. then irradiate stopped. (display 03:30:00 means it still have three hours and half till end

of irradiate.) check the time :press  5 seconds, timer display cumulative time, then auto change former value.(attention ,the unit is hour, display with decimals). After the phototherapy is over, please turn off the light therapy light switch and unplug the power plug.

c) Tip:

1. Normal timing is incremental timing, which displays the time of this phototherapy, the longest word is 100 hours; the timing is decrement timing, which displays the remaining time of phototherapy, the maximum is 48 hours.
2. After the power is turned off (turn off the switch), the phototherapy time will automatically reset to zero, and the accumulated timing information will be permanently memorized, unless the "clear" button is used to reset it to zero.

6.2.2 Introduction for functions of downside phototherapy panel

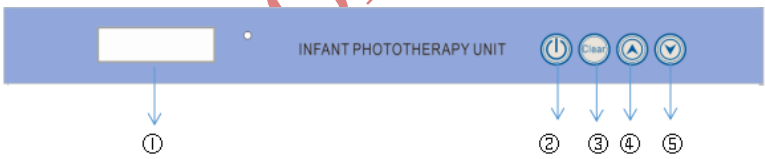


Figure 6-4 Downside phototherapy unit operation panel

1. Time display window-display each treatment time and total cumulative time.
2. “"Start/Stop" key-control the power supply of the phototherapy instrument.
3. “"Clear" key-press this key for 5 seconds, the current and accumulated time of the timer are reset to zero.

4. To set the exposure time (turn off the blue light regularly), refer to Figure 6-5:

a) Press and hold the  key for 5 seconds to enter the countdown setting mode. The default countdown time is 1 hour. If you want to change this time, you can press the  key or press the  key to increase or decrease the countdown lighting time. The lighting time that can be set is: 30 minutes × n (n=1～96), and it is displayed as 0 when n=97, that is, the setting range of the irradiation time is: 00:30:00～24:00:00.

b) After setting the irradiation time (no matter on or paused) for 5 seconds, the phototherapy instrument will automatically run at the lowest level of irradiation intensity; the timer display will gradually decrease the set time (that is, count down) until the display is 0, and the irradiation will stop. (If "03:30:00" is displayed during the countdown, it means that there are 3 hours and 30 minutes before the end of the illumination)

c) Lightly press the blue light switch  , the phototherapy unit can glow, the timer on the panel starts timing, the phototherapy starts, and the digital tube directly displays the time of this phototherapy, the maximum time of this phototherapy is 100 hours (or turn off the switch) after the phototherapy and timing the end.

Note: Children's body temperature should be checked regularly during phototherapy. And according to the situation to give the baby appropriate supplement liquid.

The phototherapy timer has a "phototherapy countdown" function. Press the  key once to reset the displayed time to zero, and continue to press this key to set the countdown time. Each time you press it, the setting time increases by 30 minutes, and the setting time range is: 0.5 to 24 hours.

View the accumulated time: press and hold the  key, the display window will display the accumulated timing time, release the key to restore the original format. (Note that the displayed value is decimal, and the unit is: hour)

After pressing the "Clear" button for a few seconds, the current use time will be reset to "0".

After shutting down, the timer will automatically add this phototherapy time to the previous accumulated time and save it as the total accumulated time, providing reliable time data for lamp replacement.

Note: Children's body temperature should be checked regularly during phototherapy. And according to the situation to give the baby appropriate supplement liquid. Intermittent radiation therapy can be implemented when necessary.

6.3 Function check

After the phototherapy device is installed and the parts are disassembled and reinstalled for each cleaning or maintenance, and before use, the baby blue light therapy device must be checked for its function to ensure that the device is working properly.

1. Button function

Before starting up, check each button for damage and abnormal pressing.

2. Timer function

After powering on, observe whether the timer display resolution and displayed content are normal.

3. The working status of the upper blue LED lamp beads

After turning on, use the irradiation intensity adjustment button to observe whether the number of corresponding LED lamp beads is in accordance with the description in 4.1 when in the high, medium and low gears.

7 Precautions

7.2 Can only be used by appropriately trained personnel and qualified medical personnel who are familiar with the existing known risks and benefits of using the equipment

7.3 The use of phototherapy equipment may affect the patient's body temperature. It is necessary to measure the patient's body temperature; phototherapy may also affect the water balance of some patients. In order to prevent patients from being dehydrated, appropriate supplementary fluids are required.

7.4 The distance between the upper blue light and the effective surface is adjustable. When the distance is shortened, the power density of blue light irradiation will increase, but it will also increase the temperature of the radiation area. Therefore, a suitable radiation distance must be selected; it is recommended to keep the distance between the baby mattress and the upper blue light Between 410mm and 570mm.

7.5 The use of phototherapy equipment in thermotherapy devices (such as incubators, radiation heaters, heating mattresses) increases the amount of heat supply, which will affect the patient's body temperature and may increase the patient's body temperature. Therefore, when performing phototherapy, the temperature of the child must be measured regularly.

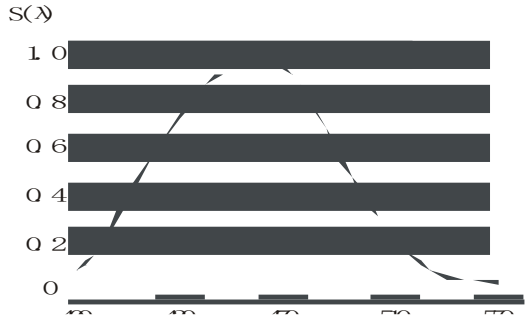
7.6 When using infant incubators, infant radiant warmers or heated mattresses, it is recommended to use the infant skin control mode. Otherwise, according to the body temperature measurement result, the setting value of the air temperature in the incubator or the setting of the heat output of the radiant warmer or the setting of the heat output of the heated mattress must be reduced.

7.7 The service life of the LED lamp beads is 50000 hours. When the cumulative work of the lamp beads reaches the expected life, all the LED lamp beads must be replaced to ensure the treatment effect. When replacing the lamp beads, the special LED lamp beads designated by the manufacturer must be used, otherwise the safety and effectiveness of the phototherapy equipment will be affected.

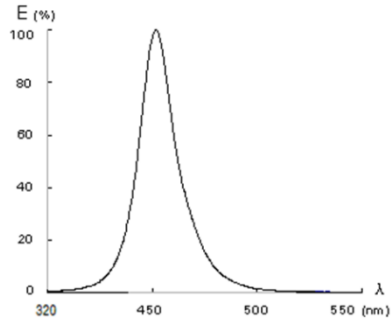
7.8 The maintenance period of LED lamp beads is 2 months, to ensure that all LED lamp beads are replaced after the total bilirubin irradiance has attenuated by 25%.

7.9 As the distance between the phototherapy equipment and the effective surface increases, the average value of total bilirubin irradiance will decrease; as the distance decreases, the average value of total irradiance will increase.

The figure below shows the irradiance curve with a wavelength range of 320nm to 550nm and an interval of 5nm.



7.10 The calibration curve of the blue radiometer for measuring the total irradiance of bilirubin is shown in the figure below. The abscissa represents the wavelength of the radiation, and the ordinate represents the spectral sensitivity of the blue radiometer.



7.11 During phototherapy, photoisomers of bilirubin may cause toxic effects.

7.12 Patients who are close to the phototherapy equipment may need protection, and protective measures such as protective covers and goggles should be provided in time.

7.13 During phototherapy, the patient's bilirubin value should be measured regularly.

7.14 As long as the eyes of the patient may be exposed to the radiation of the phototherapy equipment, immediately provide the patient with an eye shield for protection.

7.15 The preheating time of the equipment is 30min.

7.16 Protective devices (such as cribs, guard rails, front doors, etc.) that are expected to prevent the patient from leaving the effective surface area must be regularly checked for their safety functions.

7.17 Changes in the environmental conditions around the patient (such as ambient temperature, different radiation sources, etc.) will affect the treatment effect.

7.18 The service life of this equipment is 6 years. After the expiration date, if discarded randomly, it will cause damage to the local environment. Therefore, it must be disposed of in accordance with local laws or returned to our company for disposal.

7.19 he brake casters must be locked during use to prevent the equipment from moving; after selecting the appropriate radiation distance and radiation angle, the threaded handle must be tightened to prevent the light box from turning or moving up and down.

7.20 The surface of the lens must be cleaned frequently; if used with an incubator, the plexiglass on the top of the infant compartment should be kept clear to ensure the effect of phototherapy.

7.21 Only the parts designated by our company (including adapters and LED lamp beads) can be used for product maintenance, otherwise the safety and effectiveness of the equipment will be affected.

7.22 For neonates suffering from severe jaundice, phototherapy should be combined with drugs, or even combined with exchange blood therapy, to prevent the unsatisfactory effect of phototherapy alone from affecting the treatment of children.

7.23 When observing the baby's skin color for diagnosis, a white light source should be used to prevent the use of blue light from affecting the skin color observation.

7.24 Do not use it in an environment with portable and mobile radio frequency communication equipment, so as not to affect the normal operation of the product.

7.25 This equipment is only used for blue light irradiation treatment and does not have the function of heat preservation. An opaque curtain can be used to shield the equipment for protection and also have a certain warmth for the patient. The shielding will affect the care and observation of the child by the nursing staff. It is recommended to increase the frequency of monitoring children, and if necessary, keep the transparent observation window for real-time observation.

8 Warning

8.2 Selama fototerapi, mata anak-anak harus ditutup dengan kain hitam buram atau kacamata harus dipakai untuk menghindari kerusakan pada retina pasien selama penerangan. Kekencangan kacamata harus sesuai.

8.3 Selama fototerapi, kulit anak harus terbuka, topi dan kaus kaki juga akan mempengaruhi efek fototerapi, popok harus digunakan untuk menutupi alat kelamin untuk mencegah kerusakan fungsi alat kelamin.

8.4 Operator dapat terpengaruh jika ia terlalu lama berada di area penyinaran perangkat terapi cahaya.

8.5 Dilarang menggunakan bahan yang mudah terbakar (pengawet, bahan pembersih, dll.) pada peralatan fototerapi.

8.6 Dilarang menyimpan obat-obatan dan suntikan di area radiasi peralatan fototerapi.

8.7 Peralatan terapi cahaya tidak dapat digunakan dengan adanya gas pendukung pembakaran (seperti oksigen, oksida nitrat, gas anestesi). Dilarang keras meletakkan benda di kotak radiasi peralatan, belum lagi zat cair, dan dilarang keras menutupi lubang pembuangan panas kotak radiasi.

8.8 Selama fototerapi, reaksi merugikan seperti suhu tubuh abnormal, diare, ruam kulit, dan sindrom perunggu dapat terjadi. Staf medis harus memperhatikan situasi anak dan mengambil tindakan pengobatan yang sesuai untuk reaksi yang merugikan.

9. Cleaning and maintenance

Warning: Before performing cleaning and maintenance, you must cut off the link with the power supply and turn off all power switches.

9.1 Cleaning

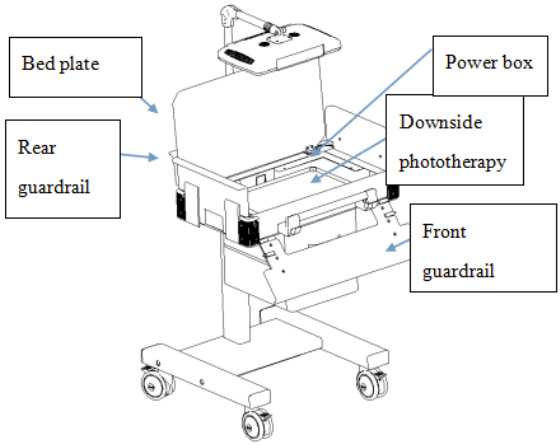
The equipment must be thoroughly cleaned and disinfected when the equipment is used for the first time, or after the irradiation of an infant is completed, or when the equipment has been used continuously for one week.

It is recommended to use a neutral disinfectant (such as 84 disinfectant) for disinfection in accordance with the dilution concentration and time specified in the disinfectant instruction manual.

Disassemble the device according to the following methods:

As shown in the figure below, turn down the front guardrail board, take out the blue light mattress, turn the rear guardrail back, and then turn the bed tray upwards. At this time, the downside phototherapy can

be adjusted as needed. , Lift up with a certain strength, unplug the phototherapy adapter connector, and then take out the Blu-ray.



- Cleaning and disinfection of the outer surface of the equipment:

First use a clean cloth to wipe all surfaces, including corners and edges, and then wipe and disinfect with a cloth moistened with a disinfectant, and finally wipe dry with a disinfectant cloth. In particular, the light-transmitting surface of the equipment must not be polluted by dirt and keep it clean and bright.

Cleaning and disinfection of cribs:

1. Take out the mattress.
2. First use a clean cloth to wipe all surfaces of the crib thoroughly, then wipe and disinfect with a cloth moistened with a disinfectant, and finally wipe dry with a disinfectant cloth.
3. Cleaning and disinfection of mattresses:

9.2 Maintains

When the machine is not in use, unplug the power plug and do not connect to the mains power supply. Wipe the surface of the machine with a clean cloth, especially the transparent surface must not be polluted by dirt to keep it bright and clean. When not in use, use a breathable cloth cover to cover the unit for storage.

1. Replacement of fuse tube:

This machine uses a T1AL 250V, Φ5×20 fuse tube. When replacing the fuse tube and repairing, you must first unplug the power cord, then pull out the fuse box, take out the broken fuse tube, and the professional should use the same model fuse tube Replace it (see figure below).

2. Maintenance of LED lamp beads:

The total bilirubin irradiance of the equipment should be tested at least once every 2 months. The test should be performed by authorized personnel with sufficient professional knowledge and practical experience or contact the manufacturer for testing. If the total bilirubin irradiance is attenuated by 25% , All LED lamp beads should be replaced immediately and replaced by professionals.

3. Maintenance of the whole machine:

The following inspections of the equipment should be carried out at least once every 12 months, and tested by authorized personnel with sufficient professional knowledge and practical experience or contact the manufacturer for testing. If it is unqualified, it must be repaired.

√ Check the integrity of the mechanical structure and function.

√ The protective grounding resistance impedance of the test equipment should not exceed 0.1Ω

√ The earth leakage current of the test equipment should not exceed 500μA under normal conditions, and should not exceed 1000μA under a single fault.

√ The shell leakage current of the test equipment should not exceed 100μA under normal conditions, and should not exceed 500μA under a single fault.

√ The patient leakage current of the test equipment should not exceed 100μA in AC and 10μA in DC under normal conditions.

√ The patient leakage current of the test equipment should not exceed 500μA in AC under a single fault condition, and the DC should not exceed 50μA under a single fault condition.

√ The patient leakage current of the test equipment, (applied part of the grid voltage), should not be greater than 5000μA under a single fault.

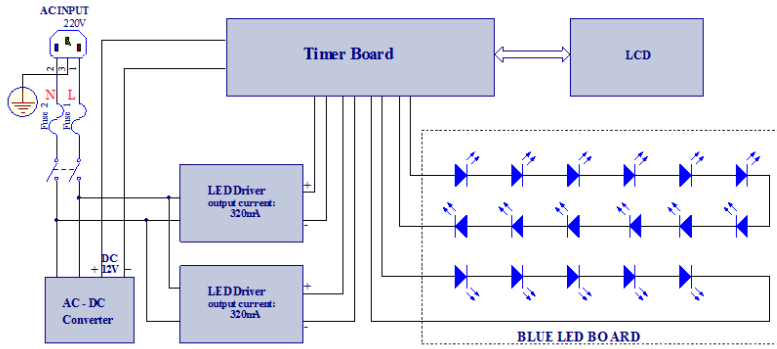
√ The patient auxiliary current of the test equipment should be no more than 100μA in AC and no more than 10μA in DC under normal conditions, and no more than 500μA in AC and no more than 50μA in DC under a single fault.

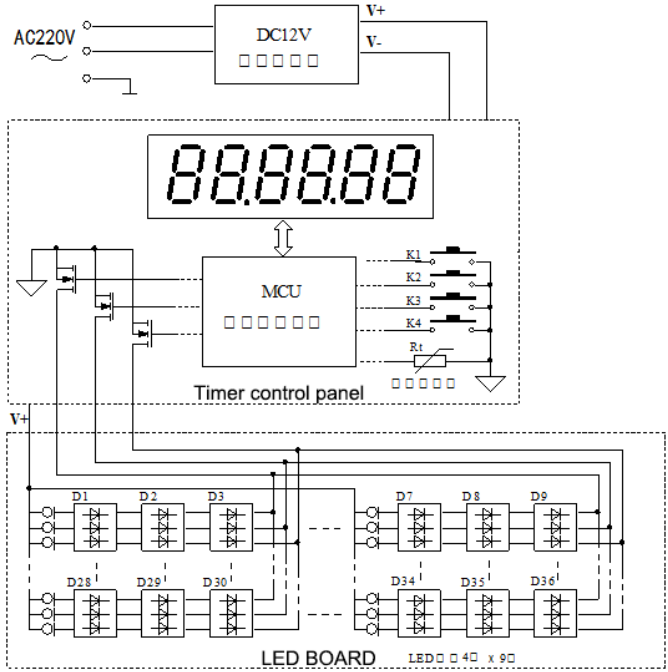
√ The parameter index in the parameter table listed in other manuals.

10. General troubleshooting

Problem	Cause analyze	Solutions
All the LED lamps are not lightening	1.Connectors of the wire are not insert well 2. The fuse is fail 3.The adapter is broken 4.the equipment with paused state	1.Insert the connectors well. 2.Change the fuse. 3.Change the adapter. 4.press key 
Plug in, some LED lamps are not lightening	1.LED lamps are broken 2.Element protection	1.Change the LED lamp 2. Inspect the circuit.
Calculagraph are not lightening	1.Line panel get loose 2.Circuit board break down.	1.Weld the lines well 2.Change for a new circuit board.

11. Schematic circuit diagram





If necessary, you can provide circuit diagrams, component lists, legends, calibration rules, or other information necessary for qualified technicians to help users repair equipment parts designated by the manufacturer as repairable.

12. Quality Commitment and Disclaimer

12.1 Quality Commitment

If the product described in this manual is defective in material and workmanship, it will be guaranteed for one year from the date of leaving the factory, except in the following cases:

1. All consumables and disposable items are only guaranteed free of charge for defects in delivery.

2. Confirm that it is normal maintenance and not included in the 1-year warranty period.

During the warranty period, in addition to those listed above, any defective parts can be replaced free of charge for the user.

12.2 *Disclaimer*

If the following conditions are found, the quality commitments proposed above are invalid, and the company does not assume any responsibility for the impact on the safety, reliability and performance of the equipment:

Failure or damage caused by the user's failure to maintain the product in accordance with the methods specified in this manual.

Failure or damage caused by user's wrong operation.

Failure or damage caused by not using parts designated by our company during maintenance or modification.

Failure or damage caused by purchase through unauthorized dealers or repairers.

Failure or damage caused by unauthorized repairers.

Failure or damage caused by unexpected events such as force majeure.

13. Electromagnetic Compatibility

BL-200 Infant Phototherapy Unit Electromagnetic Compatibility Guide and Statement

1. For this equipment, special precautions regarding electromagnetic compatibility (EMC) must be taken, and it must be installed and used in accordance with the electromagnetic compatibility information specified in this manual.

Portable and mobile radio frequency communication equipment may affect this equipment.

The cables and accessories provided by this device must be used. The cable information is as follows:

Cable name	length
Power cable	2.0m
Angle power cord	1.5m

3. Except for cables (transducers) sold as spare parts of internal components, the use of accessories and cables (transducers) other than those specified may result in an increase in the emission of the equipment or system or a decrease in immunity.

4. The equipment or system should not be used close to or stacked with other equipment. If it must be used close or stacked, it should be observed to verify that it can operate normally under the configuration used.

5. Basic performance:

Name	Specific description
Total bilirubin irradiance	1. Normal operation will not be affected if the equipment is turned on normally 2. In the corresponding standard interference state, the radiation light source does not appear not bright, flashing and other phenomena.

6. In order to ensure that the BL-200 infant blue light therapy device can be used normally and that its emission will not be increased and the immunity will not be reduced, please use the connecting cable and related accessories provided by our company.

7. The use of non-specified accessories or cables together with the BL-2000D Infant Blue Light Therapy Apparatus may result in an increase in the emission of the equipment or system or a decrease in immunity.

APPENDIX 1 Guidelines and declarations-electromagnetic immunity

Guidance and declaration-electromagnetic emissions		
The model BL-200 Infant phototherapy Unit is tended for use in the electromagnetic environment specified below. The customer or the user of the model BL-200 Infant phototherapy Unit should assure that is used in such an environment.		
Emission test	Compliance level	Electromagnetic environment-guidance
RF emission CISPR 11	Group1	The BL-200 baby blue light therapy instrument only uses radio frequency energy for its internal functions. Therefore, its radio frequency emission is very low, and the possibility of causing interference to nearby electronic equipment is very small.
RF emission CISPR 11	Class A	The BL-200 baby blue light therapy device is suitable for use in non-domestic and all facilities that are not directly connected to the public low-voltage power supply network of domestic residences.
Harmonic emission IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

APPENDIX 2 Guidelines and declarations-electromagnetic immunity

Guidance and declaration-electromagnetic immunity			
The model BL-200 Infant phototherapy Unit is tended for use in the electromagnetic environment specified below. The customer or the user of the model BL-200 Infant phototherapy Unit should assure that is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines No application	Mains supply quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential	±1kV differential	Mains supply quality should be

	mode ±2kV common mode	mode ±2kV common mode	that a typical commercial or hospital environment.
Voltage dips, short interruptions and Voltage variations on power supply input lines IEC 61000-4-11	*<5%U (>95% dip in U) for 0.5 cycle 40%U (60% dip in U) for 5 cycle 70%U (30% dip in U) for 25 cycle <5% U (>95% dip in U) for 5s*	*<5%U (>95% dip in U) for 0.5 cycle 40%U (60% dip in U) for 5 cycle 70%U (30% dip in U) for 25 cycle <5% U (>95% dip in U) for 5s*	Mains supply quality should be that a typical commercial or hospital environment
Note: U is the a.c. mains voltage prior to application of the test level.			

APPENDIX 3 Guidelines and declarations-electromagnetic immunity

Guidance and declaration-electromagnetic immunity			
The BL-200 Infant phototherapy Unit is tended for use in the electromagnetic environment specified below. The customer or the user of the model BL-200 Infant phototherapy Unit should assure that is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment

Conducted RF IEC 61000-4-6	3V rms 150KHz-80 MHz	3V rms	should be used no closer to any part of the model BL-200 Infant phototherapy Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 80MH z to 800MHz 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the
Radiated RF IEC 61000-4-3	3V/m 80MHz-2.5 GHz	3V/m	

			compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 At 80MHz and 800MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strength from fixed transmitters, such as base stations for radio telephones and land mobile radios. amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Model BL-200 Infant phototherapy Unit is used exceeds the applicable RF compliance level above, the model BL-200 Infant phototherapy Unit should be observed to verify normal operation. If abnormal performance is observed, additional

A: measures may be necessary, such as re-orienting or relocating the Model BL-200 Infant phototherapy Unit.

B: Over the frequency range 150KHz to 80MHz, field strength should be less than 3V/m.

APPENDIX 4 Guidelines and declarations-electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the BL-200 Infant phototherapy Unit

The BL-200 phototherapy device is expected to be used in an electromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile radio frequency communication device (transmitter) and the BL-200 infant phototherapy device.

Rated maximum output power of transmitter (W)	Jarak pisah menurut frekuensi pemancar (m)		
	150kHz-80MHz $d=1.2\sqrt{P}$	80MHz-800MHz $d=1.2\sqrt{P}$	800MHz～2,5GHz $d=2,3\sqrt{P}$
0,01	0.12	0.12	0,23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects

and people.

INFANT PHOTOTHERAPY UNIT

BL-200

MANUAL BOOK

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